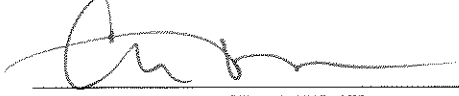
	OFFICE OF RESEARCH AND SPONSORED PROGRAMS <i>Division of Research Compliance</i>	Institutional Animal Care and Use Committee Standard Operating Procedures	
	Title: Amendment Requests in Cayuse Animal Oversight		
Effective Date:	7/23/2024	Document Number:	IACUC-SOP-013.01
Approval/Date:			
		23 July 2024	
Chad W. Hargrave Vice President & Chief Research Officer		Date	
REVISION HISTORY			

PURPOSE

The SHSU IACUC is responsible for assuring that all animal use activity meets federal regulations, policies, and recommendations. The SHSU IACUC must therefore review and approve all proposals for animal use. It is the responsibility of the Principal Investigator (PI) to submit all proposals and modifications accurately and receive approval prior to conducting any animal work.

SCOPE

Modifications should be submitted through the Cayuse Animal Oversight amendment process in the same manner as an initial Animal Use Protocol (AUP) submission. Amendments should be approved in writing prior to any changes being implemented in a study (See IACUC-SOP-011.01 AUP Approval Methods).

- A. Modifications are reviewed administratively for completeness and compliance with regulations and then may go through a Designated Review, Full Committee Review, Veterinary Verification and Consultation (VVC), or an Administrative Handling (AH) process for approval.
- B. Documentation of all amendments will be retained, and those approved administratively and via VVC will be reported at the next convened IACUC meeting.

DEFINITIONS AND ABBREVIATIONS

- SHSU- Sam Houston State University
- IACUC- Institutional Animal Care and Use Committee
- OLAW- Office of Laboratory Animal Welfare
- USDA- United States Department of Agriculture
- AVMA- American Veterinary Medicine Association
- SOP/SOP's- Standard Operating Procedure(s)
- AUP- Animal Use Protocol
- PI- Principal Investigator
- Co-PI- Collaborating Principal Investigator
- DR-Designated Member Review
- FCR- Full Committee Review
- VVC- Veterinary Verification and Consultations Review

PROCEDURE

I. Amendment Requests

- A. Modifications should not change the objectives, purpose, or aims of the original protocol. Changes of this nature should be considered a new study and submitted as a new Animal Use Protocol (AUP).
- B. Amendments should be used to correct problems or modify the study design to better achieve the goals of the approved study.

II. Minor Modifications

- A. Minor Modifications may be approved through the Administrative Handling (AH) process by the Institutional Animal Care and Use Committee (IACUC). The IACUC may delegate this AH process to the IACUC Administrator or the IACUC office. Minor modifications may include changes in:
 1. Personnel additions or deletions (aside from the Principal Investigator (PI)), which includes CITI training verification
 2. Increase in previously approved number of animals
 3. Animal sourcing
 4. Location changes within IACUC approved labs
 5. Title changes
 6. Correction of typographical and other grammatical errors
 7. Contact information updates
 8. Reporting funding changes

III. Major Modifications

- A. Significant changes to an approved AUP will go through an administrative review and will then be processed by Designated Review (DR), Full Committee Review (FCR), and in some cases Veterinary Verification and Consultation (VVC).
 1. Modifications that require DR or FCR include, but are not limited to, changes in:
 - a) PI or Co-PI
 - b) Unaffiliated research personnel
 - c) Animal numbers
 - d) Animal species
 - e) Classification under USDA pain and distress categories
 - f) Methods of restraint
 - g) Invasive procedures
 - h) Tissue or blood collection
 - i) Data collection methods or time-points
 - j) Drug or treatment changes
 - k) Methods of euthanasia
 - l) Additional procedures during terminal surgery or post-euthanasia
 2. Some significant modifications may be approved through VVC by the SHSU Attending Veterinarian or appropriate designee.
 - a) The Attending Veterinarian, as subject matter expert, will determine if a requested change meets the criteria described by OLAW and this procedure for VVC approval and holds the discretion to approve the request or require the request go through DR or FCR at any time.

- b) Significant changes that **may not be approved via VVC** include changes:
 - i. From a non-survival surgical procedure to a survival surgical procedure
 - ii. Resulting in greater pain, distress, or degree of invasiveness
 - iii. To add a new procedure type
 - iv. In housing or use/procedural locations not currently approved by SHSU IACUC
 - v. In species
 - vi. That may impact personnel safety
- c) Significant changes that may be approved via VVC, provided they do not violate the above constraints, include changes:
 - i. In dosing or agents administered for anesthesia, analgesia, sedation, or experimental substances.
 - ii. In the method of euthanasia to another AVMA-approved method.
 - iii. In the duration, frequency, type, or number of experimental procedures provided they are to substitute equivalent or improved procedures that may result in improved animal well-being and/or data collected.
 - iv. Requesting additional animals provided the increase is not more than 10% greater than the original approved number and the species is not one regulated by USDA.
 - v. In housing of animals not regulated by the USDA as long as the space meets minimum requirements as specified in the Guide for the Care and Use of Laboratory Animals.

REFERENCES

1. SHSU IACUC Policies and Procedures
2. OLAW PHS Policies
3. The Guide for the Care and Use of Laboratory Animals
4. AVMA methods for euthanasia

APPENDICES

1. IACUC Standard Operating Procedures
2. SHSU IACUC Amendment Form (Cayuse Animal Oversight)
3. Cayuse Help Articles